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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/129,298	08/05/1998	CHARLES J. ARNTZEN	7991-023-999	4312

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/129,298

Applicant(s)

ARNTZEN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the reply filed on 23 December 2003.
2. Those issues not specifically addressed in this Office action have been corrected by Applicant's amendment to the specification.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-4 and 8-27 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making a localized mutation in a target plant ALS gene or a transgenic GFP gene *in situ* in a plant cell, does not reasonably provide enablement for a method of making a localized mutation in any target gene in a plant cell. This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 September 2003. Applicant's arguments filed 23 December 2003 have been fully considered but they are not persuasive.

Applicant argues that plant mismatch repair is no less predictable than mismatch repair seen in mammalian or fungal cells and that the performance efficiency of the mismatch repair may vary between organisms but they are no less predictable because the mismatch repair does in fact work. Applicant argues that what is important is that the molecules of the present invention engage the mismatch repair system with predictable reliability and that this has been demonstrated by the examples given in the specification and numerous publications by artisans with ordinary skill in this art. Applicant further argues that the proof that it works is that routine methods can be used

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to identify the proper mutants and the undesired mutants and that the presently claimed process is predictable (Page 3 of the Remarks). These arguments are not found to be persuasive because, as previously stated by the Examiner, the state of the art at the time of Applicant's invention was not predictable as outlined by Hohn and Puchta (1999). In addition, at claims 1 and 16, the methods are directed to making any localized mutation in a plant cell to any target gene having a known sequence. Applicant has provided very limited guidance on how to use the claimed method in a plant cell as broadly claimed. In addition, the identifying step of claims 1 and 16 would require undue trial and error experimentation to practice such an identifying step as broadly claimed.

Applicant argues that US Patents 5,731,181 and 6,528,700 both contain generic claims to gene repair methods that are not limited to specific genes exemplified in their specifications (page 4 of the Remarks). This argument is irrelevant to the instant rejection because the Examiner cannot address the issue of enablement of an issued US Patent. In addition, each application is examined upon its own merits.

Claim Rejections - 35 USC § 102

5. Claims 1 and 16 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Svab *et al* 1990 (Proc. Natl. Acad. Sci. USA 87:8526-8530). This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 September 2003. Applicant's arguments filed 23 December 2003 have been fully considered but they are not persuasive.

Applicant argues that the presently claimed process encompasses mismatch repair mechanisms to make targeted mutations in known plant genes where as Svab *et al* employ nuclear transformation insert a complete cassette randomly somewhere in the plant nuclear genome and that these two processes have little, if anything in common. Applicant argues that the recombinagenic oligonucleobases [sic] of the present invention contain RNA and modified RNA. These arguments are not found to be persuasive because the instant claims do not limit the "recombinagenic oligonucleobase" to comprising RNA or modified RNA. In addition, the recombinagenic oligonucleobase of Svab *et al* would have been incorporated into the plant's plastid genome by means of mismatch repair mechanism and thus introducing the localized mutation into the plant cell to a target gene having a known sequence causing a desired trait in the plant cell as claimed by Applicant. Hence, the instant claims remain anticipated.

Claim Rejections - 35 USC § 103

6. Claims 1-4 and 8-27 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (U.S. Patent 5,731,181, filed 17 June 1996) in view of Dunder *et al* (in Gene Transfer To Plants 1995, Potrykus and Spangenberg, Eds., Springer Verlag publisher, Chapter 15, pages 127-138) and in view of Applicant's admission. This rejection is repeated for the reason of record as set forth in the last Office action mailed 23 September 2003. Applicant's arguments filed 23 December 2003 have been fully considered but they are not persuasive.

Applicant argues that because Applicants use the term "recombinagenic" in describing their small molecules to achieve mutations via mismatch repair should not be

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used against Applicant's by using nuclear transformation art to reject the present claims directed to a process of making targeted mutations (paragraph spanning pages 5-6 of the Remarks). This argument is not found to be persuasive because the teachings of Dunder *et al* is relied upon to teach that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to use a biolistic method to introduce the recombinagenic oligonucleotide taught by Kmiec into a plant cell to introduce a localized mutation into a know sequence.

Applicant argues that the present claim term recombinagenic oligonucleobase is different than the recombinagenic nucleotides used in nuclear transformation as seen in the definition provided in Section 4.1 (pp. 4-7) of the specification and therefore the nuclear transformation art of the Dunder *et al* reference cannot be properly combined with the Kmiec '181 patent relating to making localized mutations via mismatch repair (page 6 of the Remarks). This argument is not found to be persuasive because, as stated above, Dunder *et al* is relied upon to teach that introduction of nucleic acids into plant cells by adhering them to a particle was well know to one of ordinary skill in the art at the time of Applicant's invention. Kmiec suggests said method in claims 30-32 and Kmiec teaches that cells can be "transfected with the CMV" by any technique now known or to be developed for transfecting cells with DNA at column 6, lines 41-43.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
15 March 2004

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600